Immunosuppressive treatment (IST) Day 0

Guide to the completion of the EBMT data collection form:
IST_Day0_v1.0

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EBMT Registry

EBMT Clinical Research & Registry Department

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Immunosuppressive treatment day 0

The immunosuppressive treatment (IST) day 0 form should be filled in for each individual IST episode at the start of the treatment.

An immunosuppressive treatment (IST) episode is defined as any treatment combination containing one of the following components:

- **Alemtuzumab**
- **Androgens**: Danazol, Etiocholanolone, Fluoxymesterone, Nandrolone, Norethandrolone, Oxandrolone, Oxymetholone, Testosterone
- **ATG**
- **Corticosteroids**: Beclometasone, Budesonide, Dexamethasone, Methylprednisolone, Prednisolone
- **Cyclophosphamide**
- **Cyclosporin**
- **Growth factors**: Filgrastim, Lenograstim, Pegfilgrastim
- **Mycophenolate mofetil**
- **Rituximab**

IST Day 0 treatment form refers to immunosuppression and must be filled in for patients who either received immunosuppression only or immunosuppression regimen(s) before subsequent HCT.

Patients can be initially treated with androgens, steroids, cytokines or other agents. Many patients receive this type of treatment (in particular very often steroids) before being referred to a specialized treatment centre. However, this is not considered "definitive treatment" since the efficacy of this type of treatment for aplastic anaemia is very low (androgens) or absent (steroids).

Day 0

1. Date this IST episode started

Report the start date of the immunosuppression treatment episode.

2. Centre where treatment took place (CIC):

Indicate CIC of the centre where the treatment took place Acute myeloid leukaemias (AML) classification

3. Indication diagnosis for this IST episode:

Specify what primary disease is the indication for this IST episode. Make sure that respective Indication diagnosis form was filled before completing the IST Day 0 form.

4. Total number of all treatments:

Report the total number of all treatments for this patient, counting hematopoietic cell transplants, cell therapies and IST episodes.

5. Reason for this IST episode:

Select the primary reason for the IST episode from the list:

- **Indication diagnosis** (primary disease for which the reported treatment is being given, first-line);
- **Failure of first line therapy;**
- **Relapse;**
- **PR to previous treatment;**

Otherwise select **Other** and specify the indication in the textbox.

Patients often receive more than one course of immunosuppression. Sometimes patients have complex treatment history. It is important to know the reason for each IST.

Select **Unknown** if the reason for the IST episode is not known.

6. Chronological number of this IST episode:

The chronological (sequential) number of the treatment episode must be counted from the very first immunosuppressive treatment episode for the patient, which may have been already registered.

7. Ferritin level

Indicate patient's ferritin level (in **ng/ml)** before the start of this IST episode. If the ferritin level was not assessed, report **Not evaluated**. Select **Unknown** in case it is not known if the ferritin level was measured or not.

First IST episode

Complete this section (questions 8.1-8.1.4) only if this is the first IST episode ever for this patient.

8. Number of transfusions before the 1st IST episode:

8.1. Red blood cells (RBC)

Count and indicate the total number of red blood cells (RBC) units transfused before the start of IST by ticking an appropriate checkbox:

- **< 20 units;**
- **20 - 50 units;**

- **> 50 units.**

Select **None** to mark that there were no RBC transfusions. Answer **Unknown** if there is no information on RBC transfusions in the patient's medical records.

8.2. RBC irradiated

Indicate if RBC were irradiated (answer **Yes**), not irradiated (answer **No**) or if it is unknown (answer **Unknown**).

8.3. Platelets

Count and indicate the total number of platelets transfused before the start of IST by ticking an appropriate checkbox:

- **< 20 units;**
- **20 - 50 units;**
- **> 50 units.**

Select **None** to mark that there were no platelet transfusions. Answer **Unknown** if there is no information on platelet transfusions in the patient's medical records.

8.4. Platelets irradiated

Indicate if platelets were irradiated (answer **Yes**), not irradiated (answer **No**) or if it is unknown (answer **Unknown**).

Immunosuppression

Make sure you fill in the immunosuppression separately from the conditioning regimen even if the same drugs are mentioned for both treatments (e.g. ATG or cyclophosphamide may be used both for immunosuppression and conditioning). Supportive drugs given along with immunosuppression treatment in order to ameliorate side effects of treatment: e.g. corticosteroids can be reported in this section too.

9. Drugs used for immunosuppression during this IST episode (check at least one):

The list contains the main drugs for immunosuppression and supportive therapy used. Check one or more of the drug options or check the box **Other** and specify the name of a drug.

Please consult the LIST OF CHEMOTHERAPY DRUGS/AGENTS AND REGIMENS on the EBMT website for drugs/regimens names.

9.1. Product name

For Anti-Thymocyte Globulin (ATG), indicate the name of the product.

9.2. Origin

For Anti-Thymocyte Globulin (ATG), indicate the animal the product originated from.

9.3. Date started

Report the date this line of treatment was started.

9.4. Date ended

Report the date this line of treatment ended.